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### NOTICE OF ALLOWANCE AND FEE(S) DUE

26646

7590

08/01/2008

KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004

EXAMINER					
WEGERT	; SANDRAL				
ART UNIT	PAPER NUMBER				
1647					

DATE MAILED: 08/01/2008

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/802 528	03/17/2004	Lajos Hegedus	13370/53303	3513	

TITLE OF INVENTION: PHARMACEUTICAL COMPOSITIONS CONTAINING PLASMA PROTEIN

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1440	\$300	\$0	\$1740	11/03/2008

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

#### PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as a part of the current correspondence address. In the current correspondence address as a part of the current correspondence address.

maintenance fee notificat	ions.						domestic mailines of the
CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)			Texa	Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.			
26646	7590 08/01	/2008	Hav				
KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004			I he Sta add trar	reby certify that thi es Postal Service w ressed to the Mail smitted to the USPI	s Fee(s) Transith sufficient Stop ISSUE (O (371) 273-	iling or Transn smittal is being postage for first FEE address a 2885, on the da	deposited with the United class mail in an envelope above, or being facsimile to indicated below.
,							(Depositor's name)
							(Signature)
							(Date)
APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR		ATTORNEY I	DOCKET NO.	CONFIRMATION NO.
10/802,528	03/17/2004		Lajos Hegedus		13370/	/53303	3513
TITLE OF INVENTION	PHARMACEUTICAL	COMPOSITIONS CON	TAINING PLASMA PRO	TEIN			
APPLN. TYPE	SMALL ENTITY	ISSUE PEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE	FEE TOT	AL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1440	\$300	SO		\$1740	11/03/2008
EXAM	INER	ART UNIT	CLASS-SUBCLASS				
WEGERT, S	SANDRA L	1647	514-776000				
1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).  Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.  "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.			2. For printing on the (1) the names of up to or agents OR, alternating (2) the name of a sing registered attorney or 2 registered attorney or 2 registered patent attorney in the control of the control	o 3 registered patent vely, le firm (having as a agent) and the name racys or agents. If a printed.	member a	ż	
PLEASE NOTE: Uni recordation as set fort (A) NAME OF ASSIG	ess an assignee is ident h in 37 CFR 3.11. Com JNEE	ified below, no assignee pletion of this form is NO	(B) RESIDENCE: (CIT	patent. If an assign assignment. Yand STATE OR C	OUNTRY)		cument has been filed for
Please check the appropr	iate assignee category of			-			
Issue Fee Publication Fee (No small entity discount permitted)			b. Payment of Fee(s): (Ple A check is enclosed. Payment by credit ca The Director is hereb overpayment, to Dep	rd. Form PTO-2038	is attached.	d fee(s), any def	
5. Change in Entity Sta	s SMALL ENTITY state	us. See 37 CFR 1.27.	☐ b. Applicant is no los	nger claiming SMAI	L ENTITY s	tatus. See 37 CF	TR 1.27(g)(2).
NOTE: The Issue Fee an interest as shown by the	d Publication Fee (if req records of the United St	uired) will not be accepte ates Patent and Trademar	ed from anyone other than k Office.	the applicant; a regi	stered attorne	y or agent; or th	e assignee or other party in
Authorized Signature				Date			
Typed or printed name Registration No.							
			ion is required to obtain or 1.14. This collection is ey depending upon the indicate the complete properties of the complete process of the complete p				by the USPFO to process) g gathering, preparing, and ne you require to complete ritment of Commerce, P.O. for Patents, P.O. Box 1450, number.



### UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.nspto.gov

APPLICATION NO. FILING DATE		IG DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,528 03/17/2004		17/2004	Lajos Hegedus	13370/53303 3513	
26646	7590	08/01/2008		EXAM	INER
KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004		WEGERT, SANDRA L			
				ART UNIT	PAPER NUMBER
			1647		
				DATE MAILED: 08/01/200	8

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 318 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 318 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

	Application No.	Applicant(s)				
	10/002 528	HEGEDUS ET AL.				
Notice of Allowability	10/802,528 Examiner	Art Unit				
	SANDRA WEGERT	1647				
The MAILING DATE of this communication appears All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT R of the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAINS) CLOSED in this ar or other appropriate communication IGHTS. This application is subject	pplication. If not included n will be mailed in due course. THIS				
1. This communication is responsive to 7/21/08.						
2. The allowed claim(s) is/are 42-60.						
3. ☑ Acknowledgment is made of a claim for foreign priority u  a) ☑ All b) ☐ Some* c) ☐ None of the:	nder 35 U.S.C. § 119(a)-(d) or (f).					
<ol> <li>Certified copies of the priority documents have</li> </ol>	e been received.					
2.  Certified copies of the priority documents have						
3. Copies of the certified copies of the priority do	cuments have been received in this	national stage application from the				
International Bureau (PCT Rule 17.2(a)).						
* Certified copies not received:						
Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.						
<ol> <li>A SUBSTITUTE OATH OR DECLARATION must be subm INFORMAL PATENT APPLICATION (PTO-152) which give</li> </ol>	nitted. Note the attached EXAMINEI res reason(s) why the oath or declar	R'S AMENDMENT or NOTICE OF ation is deficient.				
5. CORRECTED DRAWINGS (as "replacement sheets") mu	st be submitted.					
(a) ☐ including changes required by the Notice of Draftsper	son's Patent Drawing Review ( PTC	948) attached				
1) hereto or 2) to Paper No./Mail Date		·				
(b) including changes required by the attached Examiner Paper No./Mail Date	's Amendment / Comment or in the	Office action of				
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).						
DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.						
Attachment(s)  1. Notice of References Cited (PTO-892)	5. Notice of Informal	Patent Application				
2. Notice of Draftperson's Patent Drawing Review (PTO-948)						
Paper No./Mail Date						
3. Information Disclosure Statements (PTO/SB/08).  Paper No./Mail Date						
<ol> <li>Examiner's Comment Regarding Requirement for Deposit of Biological Material</li> </ol>		nent of Reasons for Allowance				
	9.  Other					

Application/Control Number: 10/802,528

Art Unit: 1646

### **DETAILED ACTION**

The terminal disclaimer filed on 21 July 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of Patent No. 6,743,826 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Remaining claims listed as withdrawn (52 and 53) have been rejoined with claims previously examined because they now encompass allowable species of the claimed genera.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Joseph Coppola on July 31, 2008.

# The application has been amended as follows:

- 1) In claims 47, 52 and 59, please change the word "amphotericin B" to "AMPHOTERICIN B®".
- 2) In claims 47, 52 and 59, please change the word "carbamazepin" to "CARBAMAZEPIN®".
- 3) In claims 47, 52, 53 and 59, please change the word "paclitaxel" to "PACLITAXEL®".
  - 4) In claims 47, 52 and 59, please change the word "propofol" to "PROPOFOL®".

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### REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

The instant Invention is a composition of a water-insoluble pharmaceutical, such as Paclitaxel®, combined with plasma proteins, such as albumin. The composition is made by a unique process which results in unexpectedly high concentrations of drug in the mixture, stability under processing conditions including lyophilization and reconstitution, and a solution devoid of commonly-used biologically-incompatible solvents (see Inventor's publication: Paál, et al, 2001, Eur. J. Biochem, 268: 2197-2191, of record). The claims of the instant application are directed to compositions each comprising one of several anti-cancer agents, anxiolytics and antibiotics in a controlled aggregation state, combined with one or several human or animal plasma proteins. The claims are free of the prior art as the methods and compositions have not been utilized in the prior art at the solubility concentrations claimed. The specification provides experimental evidence of utility and enablement under 35 U.S.C. 112, first paragraph. The claims also meet 35 U.S.C. 112- second paragraph requirements because the claims point out and distinctly claim the invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

Application/Control Number: 10/802,528

Art Unit: 1646

fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for

Allowance."

### Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Manjunath Rao, can be reached at (571) 272-0939.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

/SLW/

31 July 2008

/Elizabeth C. Kemmerer/

Primary Examiner, Art Unit 1646